SEP 4 2012

ORTHOFIX

510(k) Summary
[as required by 21 CFR 807.92(c)]

Orthofix Galaxy Fixation System

510(k) K113770

1. **Submitted by:**

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Date Prepared July 30, 2012

2. **Device Name:**

Trade/Proprietary Name	Orthofix Galaxy Fixation System
Common Name	External Fixation Device and Accessories
Device Classification	87KTT (21 CFR 888.3030)

3. **Predicate Device:**

The Orthofix Galaxy Fixation System is substantially equivalent in intended use, materials and technological characteristics to the following external fixation systems:

- Synthes External Fixation Systems, cleared under K082650 and K090658
- Orthofix Dynamic Axial Fixation System, cleared under K955848
- Additional Accessories for the Orthofix System, cleared under K944092
- Smith & Nephew Jet-X® Bar System Clamps, Bars and Posts – MR Conditional, cleared under K072212
- Hoffmann 3 Modular External Fixation System, cleared under K111786

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4. Intended Use:

The Orthofix Galaxy Fixation System and is intended to be used for bone stabilization in trauma and orthopedic procedures, both on adults and all pediatric subgroups patients except newborns, as required.

The indications for use include:

- Open or closed fractures in long bones;
- Vertically stable pelvic fractures or as a treatment adjunct for vertically unstable pelvic fractures;
- Infected and aseptic non-unions;
- joint pathologies/injuries of upper and lower limbs such as:
    - proximal humeral fractures;
    - intra-articular knee, ankle and wrist fractures;
    - Delayed treatment of dislocated and stiff elbows;
    - Chronic, persistent elbow joint instability;
    - Acute elbow joint instability after complex ligament injuries;
    - Unstable elbow fractures;
    - Additional elbow stabilization of post-operative unstable internal fixation.

5. Description:

This Traditional 510(k) is being supplied to the U.S. FDA to provide authorization to market the device "Orthofix Galaxy Fixation System" for interstate commerce.

The Orthofix Galaxy Fixation System includes various frames, bars, clamps, accessories and instruments. The system is designed to be used with commercially available Orthofix pins. The clamps enable the frame to be coupled to bone by securing the pins/wires for the intended use.

The Galaxy Fixation System can be combined to construct different frame configurations that have been shown to be MR conditional in 1.5T and 3T MR environment. The system consists of various modules which are designed to be applied in different anatomical sites of the upper and lower limb as well as the pelvis and allow the surgeon to:

- Position screws where the condition of the bone and soft tissues permits
- Reduce the fracture in order to restore alignment
- Stabilize the fracture safely

6. Substantial equivalence:

Documentation is provided which demonstrates the Orthofix Galaxy Fixation System to be substantially equivalent to other legally marketed devices. Device comparison showed that the proposed device is substantially equivalent in intended, use, materials and performance characteristics to the legally marketed predicate devices, the Synthes External Fixation Systems, cleared under 510(k)

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K082650 and K090658, the Orthofix Dynamic Axial Fixation System (marketed as the Orthofix Procallus, Minirail System, Limb Reconstruction System, XCaliber Fixator, etc.) cleared under 510(k) K955848, Orthofix Dynamic Axial Fixation System additional accessories (marketed as the Fragment Fixation System, etc.) cleared under 510(k) K944092, the Smith & Nephew Jet-X® Bar System Clamps, Bars and Posts – MR Conditional, cleared under K072212 and testing in a Magnetic Resonance Environment safely used in Magnetic Resonance Imaging, under predetermined conditions cleared in K111786 of Hoffmann 3 Modular External Fixation System.

The components included in the Orthofix Galaxy Fixation system and the predicate devices are all external fracture fixation systems as defined in 21 CFR 888.3030, furthermore, the size, shape and materials for the subject devices are comparable to the predicate devices. Testing in accordance with ASTM 1541-02 shows the mechanical strength of the Galaxy Fixation system to be equivalent or better than the predicate devices.

6. Non Clinical testing:

Non clinical laboratory testing was performed on the Orthofix Galaxy Fixation System to determine substantial equivalence. The following testing was performed:

Mechanical performance:
- Static on Connector
- Static on Joint
- Static on Construct
- Static on Ring Segment
- Multi-cycle on Construct
- Fatigue tests on Configurations

Magnetic Resonance Environment Testing
- Radio Frequency Heating Testing
- Force and Torque Testing
- Artifact Testing

7. Conclusion:

Based upon the similarities in design, materials and intended uses, the Orthofix Galaxy Fixation System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Orthofix SRL
% Ms. Candace Cederman
Consultant
22423 Skyview Drive
West Linn, Oregon 97068

SEP 4 2012

Re: K113770
Trade/Device Name: OrthoFix Galaxy Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: August 3, 2012
Received: August 6, 2012

Dear Ms. Cederman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113770

Device Name: Orthofix Galaxy Fixation System

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  - Unstable elbow fractures;
  - Additional elbow stabilization of post-operative unstable internal fixation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113770